

ARTHUR H. KIBBE, Ph.D.
WILKES UNIVERSITY

WILKES-BARRE, PA 18766

Dr. Kibbe has a Ph.D. in Pharmacokinetics and Biopharmaceutics and a score of years working directly or indirectly with the Pharmaceutical Industry, FDA, Professional and Trade Associations and Academia. Spoke on behalf of the profession of pharmacy before Congress and the regulatory agencies. Organized and conducted successful marketing programs for two contract research organizations. Trained professional pharmacists and pharmaceutical scientists. Investigated the operations of the FDA on behalf of the commissioners. I am currently active representing several major pharmaceutical manufacturers as an expert witness in litigation.

EXPERIENCE:

WILKES UNIVERSITY, Wilkes-Barre, PA August 1994 - present
Wilkes University School of Pharmacy, Department of Pharmaceutical Sciences
Chair and Tenured Professor

- Oversaw construction of laboratory and research space in new school
- Directs a science faculty of seven Ph.D.'s.
- Resource consultant to industry on generic drug issues, regulatory affairs, international pharmaceutical manufacture
- Expert witness representing pharmaceutical companies in litigation.
- Editor-in-Chief, *Handbook of Pharmaceutical Excipients, 3rd Edition*
- Consultant to Commerce Committee, United States Congress
- Co-chair, Core Curriculum Development Committee
- Serves as Chair of Governor's Renal Disease Advisory Panel
- Member of the Food and Drug Administration's Scientific Advisory Committee

PHARMAKON RESEARCH INTERNATIONAL, INC., Waverly, Pa 1992-1994
Director of Marketing

- Developed all promotional materials, slide presentations and brochures
- Developed and implemented sales and promotion strategies that resulted in continued revenue and profit growth
- Evaluated the market, established market segments, and recommended marketing strategies for each segment
- Initiated Japanese Market Plan designed to penetrate that valuable market

AMERICAN PHARMACEUTICAL ASSOCIATION, Washington, DC 1987 - 1992
Senior Director of Professional and Scientific Affairs

- Developed and managed symposium on scientific issues

- Developed policy statements on scientific issues that impacted both pharmaceutical scientist and professional pharmacists
- Represented Association before Congress, FDA and EPA
- Managed 10 professional staff including-the Directors of Scientific Affairs, International Affairs, Professional Affairs, Student Affairs, Government Affairs and Policy
- Managed Journal of Pharmaceutical Science
- Scientific Consultant to the House of Representative's Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, as part of its review of the generic drug industry practices and the FDA's generic drug review activities
- Member of the FDA's Generic Drug Advisory Committee
- Chairman of a special panel appointed by the FDA Commissioner to investigate Fairness in the Generic Drug Approval Process, which resulted in the "Kibbe Report"

BIORESEARCH LABORATORIES LTD., Montreal, Quebec, Canada 1985 to 1987
Director of Client Services

- Managed protocol development, negotiated contracts and prices.
- Directed all the marketing and sales efforts.
- Responsible for highest division revenue and profit levels either before or since.

NATIONAL INSTITUTES OF HEALTH, Bethesda, MD 1984 to 1985
Chief of Pharmaceutical Development Services

- Directed a staff of 15 scientists
- Developed delivery systems for Phase I clinical trials.
- Controlled the use of all investigational drugs in the NIH intramural program
- Provided pharmacokinetics and analytical support for NIH intramural clinical research program.

SCHOOL OF PHARMACY, UNIVERSITY OF MISSISSIPPI, Oxford, MS 1972 to 1984
Professor of Pharmaceutics

- Taught undergraduate and graduate level courses in formulation design and development, pharmacokinetics and physical chemistry of heterogeneous systems.
- Conducted research in the areas of formulation development, pharmacokinetics of drugs of abuse, bioequivalency evaluations and impact of formulation changes on bioavailability.
- Conducted research into the effectiveness of different teaching techniques on short term recall.
- Funded by the National Institutes of Health and the Pharmaceutical Industry.
- Provided Continuing Education Symposia to the Profession of Pharmacy.
- Produced over 30 publications in refereed Journals and many essays and articles in the professional press.

U.S. ARMY, Leavenworth, KS
Pharmacist/Director of Pharmacy Services

1969 to 1970

- Pharmacist at a 150 bed army hospital.
- Supervised two pharmacist and three technical support staff.
- Reached rank of E-5 in 11 months after induction.
- Advised the post commander on how to control drug abuse problems.

EDUCATION:

Ph.D., Pharmacy-Pharmacokinetics -
University of Florida, Gainesville, Florida
M.S. Pharmacy-
University of Florida, Gainesville, Florida
B.S. Pharmacy-
Columbia University, New York, New York

PUBLICATIONS IN PEER REVIEW SCIENTIFIC JOURNALS:

Kibbe, A.H. and Araujo, O.E., "Nuclear Magnetic Resonance and Rheological Studies of the Thixotropic Properties of Montmorillonite-Water Systems", J. Pharm Sci., 58: (1969).

Kibbe, A.H. and Araujo, O.E., "Rapid Quantitative Determination of Digoxin on the Gas Chromatograph", I. Pharm. Sci., 62: 1703-1705 (1973).

Kibbe, A.H. and Wilson, M.C., "Pharmacokinetics of Cocaine in the Rhesus Monkey", Ih Pharmacologist, 18: 158 (1976).

Wilson, M.C. and Kibbe, A.H., "Correlation Between Blood Levels and Acute Pharmacological Effects of Cocaine in the Rhesus Monkey", Federation Proceeding, 35: 506 (1976).

Bedford, J.A., Kibbe, A.H. and Wilson, M.C., "Chronic Intravenous Dosing and Blood Collection in the Unanesthetized Monkey", Pharm. Biochem. Behave., 6: 601 (1977).

Borne, R.F., Bedford, J.A., Craig, C.B., Hardin, T.C., Kibbe, A.H. and Wilson, M.C., "Biological Effects of Cocaine Derivatives I: Synthesis and Brief Pharmacological Evaluation of Norcocaine", J. Pharm. Sci., 66: 119 (1977).

Kibbe, A.H., Bedford, I.A., Borne, R.F. and Wilson, M.C., "Biological Effects of Cocaine Derivatives II: Pharmacological Evaluation of N-Allyl Norcocaine in Cynomolgus Monkeys", Pharm. Res. Comm., 9: 367-374 (1977).

Wilson, M.C., Bedford, J.A., Kibbe, A.H. and Sam, J.A., "Comparative Pharmacology of Norcocaine in M. Mulatta and M. Fascicularis", Pharmacology Biochemistry & Behavior, 9: 141-145 (1978).

Kibbe, A.H. and Maginnis, P.T., "An Evaluation of a Model for the Study of the Effects of Aerobic Exercise on Atherosclerosis", *Proceeding of the Southeastern Pharmacology Society*, 1: 21 (1980).

Chambliss, W.G., Cleary, R.W., Fischer, R.G., Jones, A.B., Skierkowski, P. and Kibbe, A.H., "The Effect of Docusate Sodium on Drug Release from a Controlled Release Dosage Form", *J. Pharm. Sci.*, 70: 11 (1981).

Fischer, R.G., Kibbe, A.H., Nicholas, W.C., Sbravati, C. and Read, V.H., "Equivalence of Various Levothyroxine Preparations", *The Journal of Family Practice*, 14: 591 (1981).

Abidi, S.E., Kibbe, A.H., Cleary, R.W., Jones, A.B. and Harland, E.C., "Pharmacokinetic Interactions of Tolazamide and Oxyphenbutazone in Dogs", *J. Pharm. Sci.*, 71: 1 (1982).

Fischer, R.G., Booth, B.H., Mitchell, D.Q. and Kibbe, A.H., "Influence of the Trivalent Influenza Virus Vaccine on Serum Theophylline Levels", *Journal of the Canadian Medical Association, CMA Journal*, 126: 1312 (1982).

Beasley, M.W., Skierkowski, P., Cleary, R.W., Kibbe, A.H. and Jones, A.B., "A Comparison of HPLC and RIA in the Determination of Content Uniformity of Digoxin Tablets", *J. Pharm. Sci.*, 72:5 505-509 (1983).

Chambliss, W.G., Chambliss, D.A., Cleary, R.W., Jones, A.B., Harland, E.C. and Kibbe, A.H., "Development and Evaluation of Enteric Coated Penicillamine Tablets", *J. Pharm. Sci.*, (1983).

Hunsinger, R.N., Kibbe, A.H. and Wilson, M.C., "The Effect of Previous d-Amphetamine Treatment on the Disposition and Lethality of Fenfluramine in the Rat", *Toxicology and Applied Pharmacology*, (1984).

Silva, B.O., Cleary, R.W., ElSohly, M.A., Jones, A.B. and Kibbe, A.H., "Kinetic Study of Hydrolysis of N-Methyl Glucarnine Salt of 8-Tetrahydrocannabinol Hemisuccinate in SemiAqueous Solvent", *J. Pharm. Sci.*, 73:6 420425 (1984).

Smith, M.C., Kibbe, A.H. and Brown, T.R., "Dermatologic Prescriptions Requiring Compounding", *J. Am. Acad. Dermatol*, II: 148-151 (1984).

Farber, M.S., Greene, R.F., Kibbe, A.H. and Gallelli, J.F., "Morphine Compatibility with Drugs Commonly Used in Patients Receiving Morphine Continuous Infusion", *American Journal of Hospital Pharmacy*, (1985).

Viegas, T.X., Kibbe, A.H., Hikal, A.H., Clear, R.W. and Jones, A.B., "An in vitro Method of Evaluating Talnaflate Release from Topical Powder", *Pharmaceutical Research*, 3: 88-92 (1986).

Kibbe, A.H., "Successful Supervision: Using Interpersonal Skills", *American Pharmacy*, 29:12 23-26 (1989).

PUBLICATIONS IN PROFESSIONAL JOURNALS:

Schondelmeyer, S.W., Mason, H.L., Schafermeyer, K.W. and Kibbe, A.H., "Pharmacists' Compensation and Work Patterns: Overview of 1988 National Survey", American Pharmacy, 29:11 25-30 (1989).

Schondelmeyer, S.W., Mason, H.L., Schafermeyer, K.W. and Kibbe, A.H., "Final Report of the National Pharmacists' Compensation Survey: 1988", American Pharmaceutical Association.

Kibbe, A.H., "A Prescription for Disaster", American Pharmacy, 30:7 (1990).

Kibbe, A.H., "Generic Drug Industry Under Attack", Florida Pharmacy Today, 55: 1 6-9 (1990).

Kibbe, A.H., "Generic Drug Industry Under Attack", The Kentucky Pharmacy, 54-57 (1990).

Kibbe, A.H., "Generic Drug Industry Under Attack", J. of Mississippi Pharmacists Association, May/June 15-19 (1990).

Kibbe, A.H., Kopf, J.A., Zarembo, J.E., "Fairness in the Food and Drug Administration's Generic Drugs Program, April 1991

Kibbe, A.H., Weaver, L.C., "Generic Drugs and Generic Equivalency" chapter in Encyclopedia of Pharmaceutical Technology Editors Swarbrick, J. and Boylan J.C., Marcel Dekker.(1993)

Schondelmeyer, S.W., Mason, H.L., and Kibbe, A.H., "Pharmacists' Compensation and Work Patterns: Overview of the 1990-91 Survey" American Pharmacy, 32:1 (1992).

Schondelmeyer, S.W., Mason, H.L., Kibbe, A.H., "Final Report of the National Pharmacists' Compensation Survey: 1990-91" American Pharmaceutical Association.

Kibbe, A.H. Contributing author, NDA Pipeline, 1994, Published in 1995.

Kibbe, A.H. Nationally reprinted editorial on the FDA approval process, various newspapers, Fall, 1995.

Kibbe, A.H. Quoted in New York Times article on the importation of drug products and the Food and Drug Administrations oversight, October, 1995.

Kibbe, A.H. Invited article, commentary on the GAO report on International Drug Classification Systems, GAO Report on Need for a Third Class: "Prove It", Journal of the American Pharmaceutical Association, 35:48 Fall, 1995.

Kibbe, A.H. "Generic Drugs and Generic Equivalency" chapter in Encyclopedia of Pharmaceutical Technology, 2nd Edition Editors Swarbrick, J. and Boylan J.C., Marcel Dekker.(1999)

Kibbe, A.H. Contributing author, Handbook of Pharmaceutical Excipients, 3rd Edition, monographs on Benzalkonium Chloride, pg. 33; Crospovidone, pg. 163; Fructose, pg. 210; Guar Gum, pg. 233; Lactose, pg. 276; Mineral Oil and Lanolin Alcohols, pg. 349; Paraffin, pg. 358; Peanut Oil, pg. 361; Povidone, pg. 433; Sodium Starch Glycolate, pg. 501; Starch, pg. 523; Sucrose, pg. 539; Sugar, confectioner's, pg. 546; Talc, pg. 555; Thimerosal, pg. 562; Wax, microcrystalline, pg. 591; Wax, white, pg. 595; Wax, yellow, pg. 597; 2000.

Kibbe, A.H. "Generic Drugs and Generic Equivalency" chapter in Encyclopedia of Pharmaceutical Technology, 3rd Edition Editors Swarbrick, J. and Boylan J.C., Marcel Dekker.(2001)

PRESENTATIONS:

Wilson, M.C. and Kibbe, A.H., "Correlation Between Blood Levels and Acute Pharmacological Effects of Cocaine in the Rhesus Monkey". Presented at the FASEB meeting in Anaheim, California, 1976.

Kibbe, A.H. and Wilson, M.C., "Pharmacokinetics of Cocaine in the Rhesus Monkey". Presented at the Fall ASPET meeting, New Orleans, Louisiana, 1976.

Kibbe, A.H. and Burdock, N., "An Evaluation of the Five Minute Quiz in Teaching Pharmacy Calculations". Presented at the Fall AACP meeting, 1976.

Kibbe, A.H., Bedford, J.A., Borne, R.F. and Wilson, M.C., "Pharmacological Evaluation of N-Allyl-Norcocaine in the Cynomolgus Monkey". Presented at Academy of Pharmaceutical Science Meeting, Orlando, Florida, November, 1976.

Kibbe, A.H. and Maginnis, P.T., "An Evaluation of Model for the Study of the Effects of Aerobic Exercise on Atherosclerosis". Presented at the first annual meeting of the Southeastern Pharmacology Society, Fall, 1980.

Kibbe, A.H., Chambliss, W.G., Fischer, R.G. and Scott, L.S., "Zomepirac Pharmacokinetics in Renal Failure Patients". Presented at the Academy of Pharmaceutical Science Meeting, April, 1982.

Beasley, M.W., Skierkowski, P., Cleary, R.W., Kibbe, A.H. and Jones, A.B., "A Comparison of HPLC and RIA in the Determination of Content Uniformity of Digoxin Tablets". Presented at the Academy of Pharmaceutical Sciences Meeting, April, 1982.

Hunsinger, R.N., Kibbe, A.H. and Wilson, M.C., "Subacute d-Amphetamine (AM) Treatment Enhances Fenfluramine (FN) Lethality in Rats". Presented ASPET/SOT, 1982.

Murphy, J.C., Kibbe, A.H., Ma, G.E., ElSohly, M.A. and Walker, L.A., "Effects of Marijuana Smoke on Cocaine Pharmacokinetics in Rats". Presented at the Southeastern Pharmacological Society Meeting, October, 1982.

Quintana, B.A., Cleary, R.W., Kibbe, A.H., Skierkowski, P. and Jones, A.B., "The Degradation of Ethylene Oxide in the Presence of Chloride Ion in Aqueous Media at pH 7.4". Presented at the Academy of Pharmaceutical Science Meeting, April, 1983.

Silva, B.O., Cleary, R.W., ElSohly, M.A., Jones, A.B. and Kibbe, A.H., "Kinetic Study of Hydrolysis of N-Methyl Glucamine Salt of 8-Tetrahydrocannabinol Hemisuccinate in SemiAqueous Solvent". Presented at the Academy of Pharmaceutical Science Meeting, April, 1983.

Bowers, C.J., Anderson, E.R. and Kibbe, A.H., "The Effects of Potassium and Magnesium Salt of Aspartic Acid on Strength, Endurance, Anthropometric, Measurements, and Body Composition of Male College Age Advance Weight Lifters". Presented at the Southern District American Alliance of HPERD, Biloxi, MS, February, 1984.

Kibbe, A.H., Anslow, J., Bohaychuk, W., Dabrowski, J., Faulkner, B., Silber, B.M. and Woodward, D., "Pharmacokinetics of Cefixine on the Fasted and Fed State". Presented at the 15th International Congress of Chemotherapy, Elmadag, Istanbul, Turkey, July, 1987.

Kibbe, A.H., "The Scientific & Professional Aspects of the Generic Drug Issue". Presented at the national meeting of the National Council for Prescription Drug Programs (NCPDP), Scottsdale, AZ, February, 1990.

Kibbe, A.H., "Generic Drugs: A Scientific and Professional Perspective". Presented at the Thirty-Fifth Annual Ohio Pharmaceutical Seminar, Columbus, OH, April, 1990.

Kibbe, A.H., Kopf, J.A., Zarembo, J.E., Testimony before Congress. Fairness in the Food and Drug Administration's Generic Drugs Program, Washington, D.C., June, 1991.

Kibbe, A.H. The Drug Approval Process - The Food and Drug Administration. Changing for the Future. Presented to Pharmacy Associations in Harrisburg and Wilkes-Barre, 1995.

Kibbe, A.H., Testimony before Congress: Subcommittee on Oversight and Investigations of the Committee on Commerce House of Representatives. U.S. Government Printing Office, Washington, D.C. Serial No. 104-23, pg. 138. June 19, 1995.

PUBLISHED BOOKS

Editor-in-Chief, Handbook of Pharmaceutical Excipients, 3rd Edition, published jointly by Royal Pharmaceutical Society of Great Britain and American Pharmaceutical Association, 2000

ACADEMIC GRANTS AND CONTRACTS:

"A Study of Biopharmaceutical Parameters Associated with Cocaine Blood Level in Primates After Self-Injection", Committee on Faculty Research of the Graduate School, University of Mississippi;

"Pharmacodynamics of Stimulant Self-Administration", PYSIROIDA01002; NIDA.

"Pharmacokinetics and Metabolism of HP 549 After Three Different Single Oral Doses to Normal Adult Males"; Hoechst-Roussel.

"Pharmacokinetics and Metabolism of HP 549 After Antacid Therapy"; Hoechst-Roussel.

EDITORIAL AND REVIEW ACTIVITIES:

Editor-in-Chief, Handbook of Pharmaceutical Excipients, 3rd Edition

Reviewer, Journal of Pharmaceutical Science (Present)

Reviewer, Journal of American Pharmaceutical Association (Present)

Consulting Editor, NDA Pipeline, 1994-1995

Editorial Review Panel, Journal of Drug Development and Industrial Pharmacy (Present)

HONORS:

Fellow of the Academy of Pharmaceutical Research and Science - 1994

Member of Rho Chi - A Pharmacy Scholarship Fraternity - 1972

Outstanding Professor of the Year - University of Mississippi School of Pharmacy - 1978

Outstanding Faculty, School of Pharmacy - Wilkes University, 1996, 2001

President-elect of the American Pharmaceutical Association's Academy of Pharmaceutical Research and Science 2001